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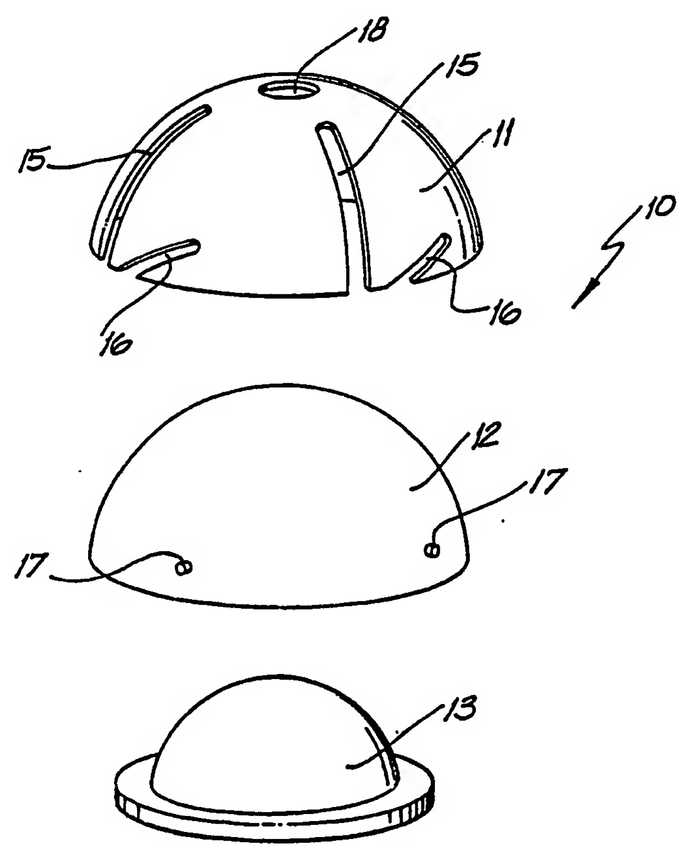
(57) Abstract

An acetabular component (10) for a hip prosthesis. The component comprises an outer shell (11) of substantially hemispherical shape, the radius of which may be increased at least in its peripheral region, and an inner non-compressible shell (12) of substantially hemispherical shape which has an outer radius slightly greater than the initial inner radius of the outer shell (11). Means, such as slots (16) in the outer shell (11) and pins (17) projecting radially from inner shell (12), to enable the inner shell (12) to be held firmly nested within the outer shell (11) and to thereby expand at least the peripheral region of the outer shell (11). In use the expansion of the outer shell (11) urges it into firm engagement with the bone (14) surrounding a suitable cavity which has been reamed in the pelvic bone.



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HIP PROSTHESIS

Field of the Invention

The present invention relates to an acetabular component prosthesis for use in a total hip arthroplasty.

Background Art

Hip replacement operations have become more common in recent years and are now being used not only for the aged but also for relatively young patients who may require hip replacement following trauma or premature degeneration of the hip. This has highlighted the need for improved fixation of the acetabular component in the pelvic bone. The acetabular component may either be cemented in place using a cement such as polymethylmethacrylate or it may be a cementless component held in place by physical engagement of the component with the bone followed, hopefully, by osseointegration, i.e. bone ingrowth into the surface of the component. Where the bone is sound the use of a cementless acetabular component is preferred. It has been found however that an unacceptable degree of late aseptic loosening occurs with both cemented and cementless acetabular components.

The human acetabulum is not hemispherical in shape. At rest, it is an eliptical structure. The pelvic acetabular bone is viscoelastic and flexible, and under load the acetabulum can deform. The deformation with load causes the acetabulum to change from the eliptical shape to a more hemispherical shape. When the load is removed the acetabulum becomes eliptical again. There is, with activity, a cyclic shape change occurring. If this pattern of cyclic change was not the case then there would be no need for a transverse ligament. The acetabular articular surface would be a complete osseo-cartilagenous ring to accommodate the femoral head. This is not the case. The acetabular articular surface is actually a horseshoe shaped structure. The osseo-cartilagenous

articular rim is deficient at the site of the acetabular fossa. It is at this site that one finds the transverse acetabular ligament. The fibres of this ligament decussate like a St. Andrew's cross. This decussation permits the transverse ligament to accommodate the cyclic change in shape of the acetabulum. The geometric change has been identified as being up to and even more than 100 microns.

Almost all uncemented hemispherical acetabular components are designed to achieve durable fixation by means of osseointegration. For bone ingrowth to occur there must be close apposition of the implant to bone and there must be stable primary fixation. There must be no micromotion. Furthermore, for bone ingrowth to be achieved, the geography of the porous surface of the implant must be of the order of a 300 micron porosity. A cyclic geometric micromotion of 100 microns will reduce the effective pore size of the implant available for bone ingrowth to 100 microns. This pore size is not compatible with bone ingrowth. Fibrous tissue ingrowth is the more likely event.

The cyclic change of the pelvic acetabular geometry implies then that under load there is an environment of compression at the implant bone interface and when load is removed there is an environment of tension. Any motion at the interface will also be associated with shear forces. The hemispherical implant-bone interface is then exposed to a complex combination of forces, i.e. compression, tension and shear. The zonal distribution of these forces is unpredictable and will be influenced by a variety of factors, e.g. the nature of the materials of fabrication, the bone quality, the dynamics of load, frictional torque, etc. The orientation of the implant is no less important. The zonal distribution of forces is greatly influenced by the abduction angle of the implanted cup.

The hemispherical acetabular component can be described as an implant whose shape presents, and is exposed to, a most unstable biomechanical environment. This environment is one which can preclude the achievement of osseointegration and thereby deny a stable and durable fixation of the acetabular prosthesis.

Biological fixation is fundamentally no different from mechanical fixation. Both are enhanced by compression and compromised by tension and shear. Biological environments characterised by tension and shear are characterised by fibrous tissue ingrowth. Osseointegration is absent or at best poor in such circumstances.

Furthermore when a rigid hemispherical device is implanted into a reamed acetabular cavity and placed under load the compression forces within the pelvic bone generate secondary compressive stresses as the pelvis changes shape. The effect of this is for there to be a tendency to push the prosthesis out from the acetabular cavity. This does not occur in practice but the effect of this biomechanical activity is a cause for micromotion that will prevent the achievement of osseointegration. When the load is removed, the elastic 'recoil' of the pelvis generates secondary tension forces. These undesirable secondary compression and tension forces are localised predominantly at the periphery of the implant.

The acetabular component prosthesis of the present invention is designed to provide an alternative to known acetabular components. In preferred embodiments, at least, it is believed that the acetabular component according to the present invention will be more resistant to micromotion between the bone and the prosthesis, and hence late aseptic loosening, than the known acetabular components.

Disclosure of the Invention

The present invention consists in an acetabular component prosthesis comprising an outer shell of substantially hemispherical shape, the radius of which may be increased at least in its peripheral region, an inner non-compressible shell of substantially hemispherical shape and having an outer radius slightly greater than the initial inner radius of the outer shell and means to enable the inner shell to be held firmly nested within the outer shell and to thereby expand at least the peripheral region of the outer shell.

The present invention is founded upon the inventor's realisation that for long term durable fixation and for osseointegration to be achieved there must be

1. excellent implant-bone apposition,
2. stable initial implant fixation,
3. exposure of the implant-bone interface to compressive stresses throughout all phases of cyclic loading and unloading, and
4. a uniform environment of compressive stress at the implant bone interface around the periphery.

It is the inventor's view that these fundamental requirements can only be achieved if the harmful effects of cyclic pelvic deformation and secondary compressive and tensile stresses can be prevented. This can be possible by the application of the engineering concept of preloading or pretensioning.

The effect of preloading or pretensioning is to place an interface (e.g. acetabular component - bone) into compression for better resistance to external tension forces and to create a friction force at the interface to resist shear forces. This is akin to a 'wedge expansion effect'. The effect will be to neutralise harmful cyclic secondary compression and tension forces, and to eliminate micromotion.

The acetabular component according to this invention

applies the basic engineering concept of preloading or pretensioning in its design, and by virtue of the unique configuration of the device. This preloading or pretensioning of the bone is retained in use by the continued outward pressure of the outer shell against the surrounding bone.

The present acetabular component prosthesis is able to generate a pretension force at the bone-implant interface on insertion which will generate hoop stresses in tension in the bone to cause the interface to be under compression and in a state of preload. This effect will be maximal and uniform at the periphery and may be achieved, if desired, without any additional fixation (e.g. PMMA cement, screws, threads, spikes or pegs).

The outer shell is preferably formed of a thin metal hemisphere with a plurality of equiangularly spaced slots extending from the peripheral region of the shell towards its polar region. This allows the peripheral region of the outer shell to be readily expanded upon nesting of the inner shell therein. The degree of expansion, as measured by increase in radius, is preferably of the order of from 0.05mm to 1.5mm.

In preferred embodiments the height of the outer shell is slightly less than its initial radius of curvature. If desired the outer shell may be provided with one or more holes to permit visualization of the prosthesis bone interface. These perforations, like the slots, function as macroporous venues for bone ingrowth. The outer surface of the outer shell may be coated with a bioactive material such as hydroxyapatite, may be sintered, have a microporous surface, or may be smooth. If desired the outer shell may also serve as a Protrusio Ring device, or bone graft retention device.

The inner shell is preferably a thick metal hemisphere which is resistant to compression such that

upon nesting of the inner shell with the outer shell it will be the outer shell which expands and not the inner one which is compressed. The inner shell preferably contains a liner of ultra high molecular weight polyethylene or a similar polymeric or ceramic material with which the head of the femoral stem prosthesis articulates. If desired the liner and/or the inner shell may be provided with means to permit fixation of the liner in the inner shell.

The inner shell is preferably of a height slightly less than its radius and the height is preferably so selected that when the inner and outer shells are nested their peripheral edges will in a substantially common plane.

The inner and outer shells are preferably formed of titanium, a titanium alloy, or an alloy of cobalt, molybdenum and chromium. While the acetabular component according to this invention is designed for use without bone cement it is possible to use cement fixation if surgical needs require this form of bond.

The means to hold the shell in nesting relationship may be formed on the inner shell, the outer shell or both and may comprise mating screw threads or wedges, or any similar means. In a preferred arrangement the means comprise a plurality of radially extending pins, threads or bosses around the periphery of the inner shell which engage with corresponding ones of a like plurality of slots formed in the outer shell. The slots in the outer shell open into its peripheral edge and are inclined to the peripheral edge.

In use, a reamer, or a series of reamers, is used to form a suitably sized cavity to receive the outer shell. In practice it is necessary for the surgeon to have available the acetabular component in a number of different sizes so that he may select the right size of

prosthesis for each patient. After the cavity has been formed the outer shell is inserted into it and the inner shell then introduced into the outer shell with its pins aligned with the slots in the outer shell. At this time it is possible to rotate the prosthesis in the cavity to get the correct alignment of the axis of the prosthesis relative to the patient's pelvis. The inner shell is then rotated relative to the outer shell. This rotation causes the pins in the inner shell to slide down the slots in the outer shell drawing the inner shell firmly into a nesting relationship with the outer shell. As this happens the outer shell is caused to flex outwardly in its peripheral region and to push against the bone surrounding the cavity thereby placing that bone in compression and simultaneously locking the prosthesis in place in the cavity.

Brief Description of the Drawings

Hereinafter, given by way of example only, is a preferred embodiment of the present invention described with reference to the accompanying drawings in which:-

Fig. 1 is a diametric sectional view through an acetabular component prosthesis according to this invention in place in a bone cavity,

Fig. 2 is an expanded perspective view of the acetabular component prosthesis of Fig. 1,

Fig. 3 is a side elevational view of the outer shell of the acetabular component prosthesis of Fig. 1, and

Fig. 4 is a side elevational view of the inner shell of the acetabular component prosthesis of Fig. 1.

Best Mode for Carrying out the Invention

The acetabular component prosthesis 10 comprises an outer shell 11, and inner shell 12 and a liner 13. As seen in Fig. 1 the prosthesis 10 is positioned within a

substantially hemispherical cavity in the pelvic bone 14.

The outer shell 11 is substantially hemispherical, is formed of titanium and has a thickness of 1mm. The outer shell 11 is sintered on its outer surface to assist osseointegration and is formed with an aperture 18 in its polar location.

Four slots 15 are arranged equiangularly around the outer shell 11. These slots 15 extend inwardly from the periphery of the outer shell part way towards its polar location. Four further slots 16 are equiangularly spaced around the inner shell and open into the periphery thereof. The slots 16 are inclined to the peripheral edge by an angle of approximately 20°. As is seen in Fig. 3 the outer shell 11 has an outer radius of 28mm and an inner radius of 27mm. The height of the outer shell 11 is 26mm on the outer surface and 25mm on the inner surface. The slots 16 have a width of 2mm and terminate 3.16mm above the peripheral edge of the outer shell.

The inner shell 12 is also hemispherical and formed of titanium. It is thick walled so as to be substantially incompressible. It is formed around its periphery with four equiangularly spaced pins 17 which are adapted to engage with the slots 16 in the outer shell. As is seen in Fig. 4 the inner shell 12 has a radius of 27.5mm and a height of 25mm. The pins 17 have a radius of 1mm and are centered 2.66mm from the periphery of the inner shell 12.

It will be recognised that the dimensions given in the foregoing paragraphs are for one specific size of the preferred embodiment of the invention, that is a 56mm component and are given by way of illustration only.

The liner 13 is formed of ultra high molecular weight polyethylene and is adapted to fit within the inner shell 12 and to receive the head of a femoral prosthesis (not shown).

In use a cavity of 56mm diameter is reamed in the

pelvic bone 14 using a conventional reamer and the outer shell 11 is placed therein. The inner shell 12 is then placed in the outer shell and rotated slightly to introduce the pins 17 into the slots 16. The angular position of the prosthesis 10 in the bone 14 may be adjusted slightly at this point. The inner shell 12 is then rotated relative to the outer shell 11. This may be done using a hand tool adapted to engage with the inner shell 12 if desired. The relative rotation between the inner and outer shells 11 and 12 causes the pins 17 to ride down the slots 16 causing the inner shell 12 to be drawn into and nest firmly in the outer shell 11. The peripheral regions of the outer shell 11 between the slots 15 are thus caused to flex radially outwardly pressing firmly against the bone 14 and placing it under a compressive force. This compressive force immobilises the prosthesis 10 in the bone 14 and prevents movement therebetween. This in turn facilitates bone growth and osseointegration between the bone 14 and the prosthesis 10.

CLAIMS:-

1. An acetabular component prosthesis comprising an outer shell of substantially hemispherical shape, the radius of which may be increased at least in its peripheral region, an inner non-compressible shell of substantially hemispherical shape and having an outer radius slightly greater than the initial inner radius of the outer shell and means to enable the inner shell to be held firmly nested within the outer shell and to thereby expand at least the peripheral region of the outer shell.

2. An acetabular component prosthesis as claimed in claim 1 in which the outer shell is formed of a thin metal hemisphere with a plurality of equiangularly spaced slots extending from the peripheral edge of the shell towards its polar region.

3. An acetabular component prosthesis as claimed in claim 1 in which the radius of the peripheral region of the outer shell may be expanded by an amount of from 0.05 to 1.5mm.

4. An acetabular component prosthesis as claimed in claim 1 in which the height of the outer shell is slightly less than its initial radius of curvature.

5. An acetabular component prosthesis as claimed in claim 1 in which the outer shell is provided with one or more holes to permit visualization of the prosthesis bone interface during installation of the prosthesis.

6. An acetabular component prosthesis as claimed in claim 1 in which the outer surface of the outer shell is smooth, is microporous, is sintered or is coated with a bioactive compound such as hydroxyapatite.

7. An acetabular component prosthesis as claimed in claim 1 in which the inner shell is a thick metal hemisphere.

8. An acetabular component prosthesis as claimed in claim 1 in which the inner shell contains a liner with

which the head of a cooperating femoral stem prosthesis can articulate.

9. An acetabular component prosthesis as claimed in claim 8 in which the liner is formed of a material selected from the group comprising a high molecular weight polyolefin and a ceramic.

10. An acetabular component prosthesis as claimed in claim 1 in which the inner shell is of a height slightly less than its radius and is so selected that when the inner and outer shells are nested together their peripheral edges lie in a substantially common plane.

11. An acetabular component prosthesis as claimed in claim 1 in which the means to hold the shells in nested relationship comprises a plurality of radially extending pins, threads or bosses around the periphery of the inner shell which engage with a like plurality of inclined slots formed to open into the peripheral edge of the outer shell.

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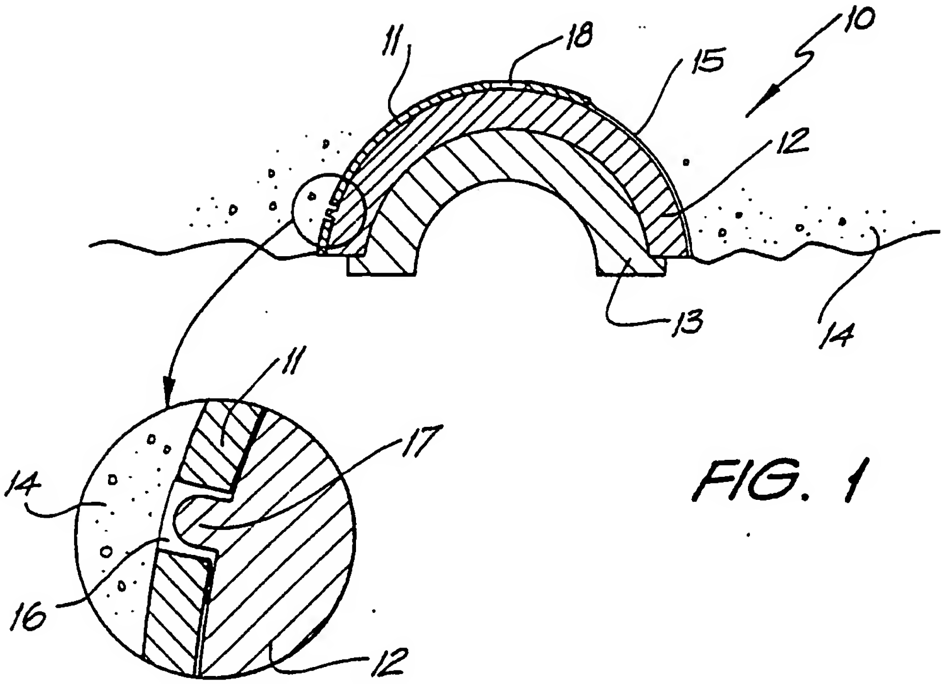

FIG. 1

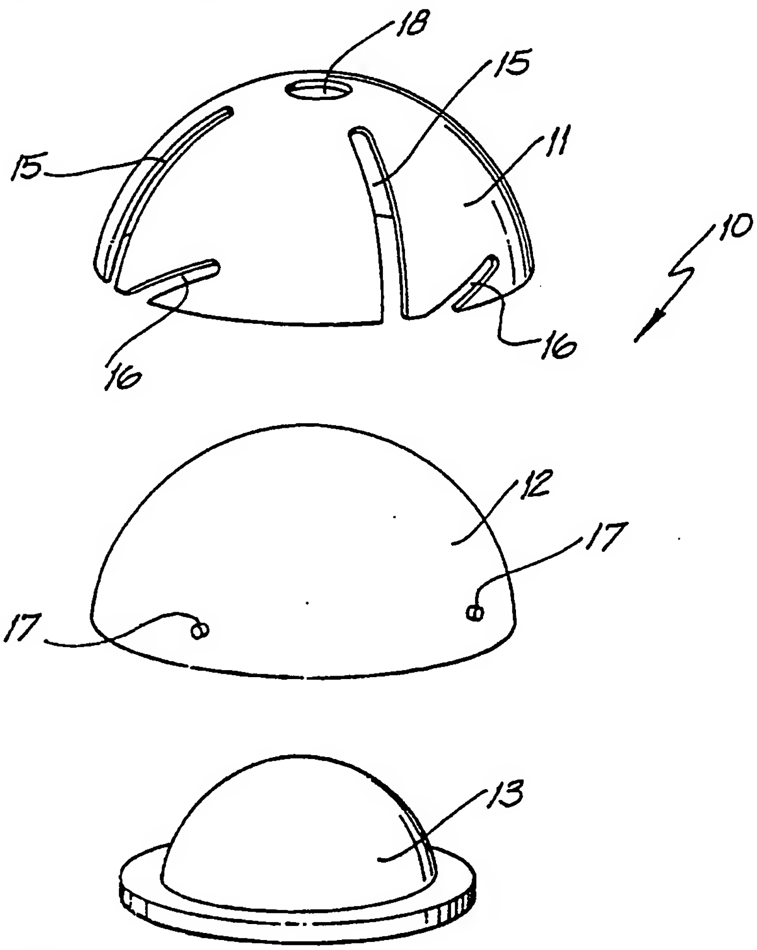

FIG. 2

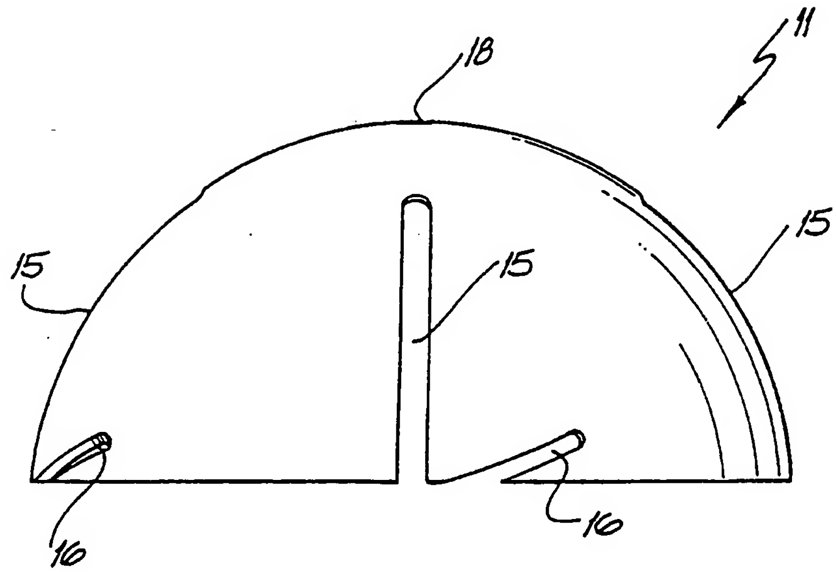

FIG. 3

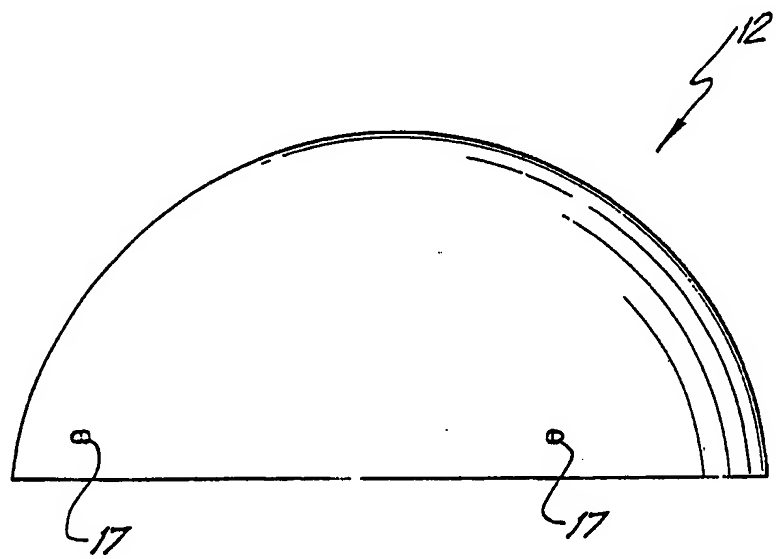

FIG. 4

International Application No. PCT/AU 92/00274

INTERNATIONAL SEARCH REPORT

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent classification (IPC) or to both National Classification and IPC

Int. Cl.[5] A61F 2/34

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC	A61F 2/34, 1/03

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

AU: IPC as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category*	Citation of Document, [11] with indication, where appropriate of the relevant passages [12]	Relevant to Claim No [13]
X	DE,A1, 3840468, (LIEKE) 7 June 1990 (07.06.90). See Figures 3 and 4	1
X	EP,A1, 353171 (FAYARD et al) 31 January 1990 (31.01.90). See column 5 lines 7-12	1-3, 5-8, 10, 11
Y	US,A, 4892549, (FIGGIE et al) 9 January 1990 (09.01.90). See column 2 lines 5-22	4
A	DE,A1, 3726213 (MECRON MED PROD GmbH) 16 February 1989 (16.02.89). See Figure 2	1

* Special categories of cited documents : [10]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
28 July 1992 (28.07.92)	12 Aug 1992 (12.08.92)
International Searching Authority	Signature of Authorized Officer
AUSTRALIAN PATENT OFFICE	A HENDRICKSON

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL APPLICATION NO. PCT/AU 92/00274

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Patent Document Cited in Search Report	Patent Family Member		
US 4892549	AU 48828/90 JP 3015458	CA 2006274	EP 381351
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EP 353171	FR 2634644		
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